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BY E-FILING AND FAX

The Honorable Joel Schneider
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Room 1050
Camden, New Jersey 08101

 PUBLIC - REDACTED VERSION

Re: Sciele Pharma, Inc., et al. v. Lupin Ltd., et al., C.A. No. 09-037-RBK-JS

Dear Judge Schneider:

Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan” or “Defendants”) oppose the untimely request by Plaintiffs Sciele Pharma, Inc., n/k/a Shionogi Inc. (“Shionogi”), and Andrx Corporation; Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc. – Florida); Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc.; Andrx EU Ltd.; and Andrx Labs, L.L.C. (collectively, “Andrx” and, collectively with Shionogi, “Plaintiffs”) to amend their infringement and validity contentions.¹ As this case’s prolonged fact discovery period finally comes to a close, Plaintiffs now want to add facts, and theories based on facts, they have long known or reasonably should have known and failed to raise until now, nineteen months after possession of these facts and twelve months after Plaintiffs amended their contentions as of right. Plaintiffs’ own actions are contrary to the good cause and diligence requirements of Local Patent Rule 3.7. Moreover, even if their actions are in line with Rule 3.7, the prejudice to Mylan would only serve to unjustifiably require: (i) an increase in Mylan’s time and resources in developing a case related to these new theories; (ii) additional depositions, particularly in view of the fact that several of Plaintiffs’ witnesses were not prepared to provide testimony regarding topics for which they had been designated; and (iii) Mylan to amend its own contentions in response to Plaintiffs’ late stage amendments. These reasons, which would all result in a need to extend a fact discovery schedule that has already been extended several times and is only a week from completion, would far outweigh Plaintiffs’ need to amend. Therefore, Mylan respectfully submits, Plaintiffs should not be permitted to supplement their contentions.

¹ Plaintiffs misrepresent their amendment as being at “the Court’s direction.” (Plaintiffs’ 02/01/2013 Letter to the Court). In reality, the Court simply stated the obvious, that “[t]he patent rules provide that you have to file a motion to supplement contentions.” (11/29/2012 Hearing Tr. at 7:20-22).

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I. Factual Background

Plaintiffs brought this patent infringement suit against Mylan for its filing of an Abbreviated New Drug Application (“ANDA”) for a generic equivalent of the Fortamet® metformin product. The relevant facts pertinent to this letter include the following²:

- On September 14, 2010, Mylan served invalidity contentions on Plaintiffs. Barry Decl. ¶ 2;
- On May 9, 2011, Matrix Laboratories Ltd. (“Matrix”), who is not a party to this litigation, but a subsidiary of Mylan, produced documents Bates labeled MATA00000001-MATA0012670. Barry Decl. ¶ 3. Among the documents produced was the Indian Patent Application filed by Matrix and Bates labeled MATA00012345-MATA00012368. *Id.*;
- On February 29, 2012, Plaintiffs served supplemental infringement contentions (“Infringement Contentions”) (D.I. 358) in accordance with the deadline set by the Court’s December 16, 2011, Amended Scheduling Order. Barry Decl. ¶ 4. Plaintiffs’ Infringement Contentions made no reference to the Indian Patent Application. *Id.*;
- On March 20, 2012, without seeking leave of Court, Plaintiffs served ineffectual “responsive” validity contentions purportedly responding to validity contentions Mylan had served eighteen months earlier in September 2010 (D.I. 379). Barry Decl. ¶ 5;
- On August 15, 2012, again without seeking leave of Court, Plaintiffs served ineffectual “Second Supplemental” infringement and invalidity contentions (D.I. 538), that they contend were based on the purported need to respond to supplemental interrogatory responses served by Mylan and Lupin (D.I. 636 at 3). Barry Decl. ¶ 6; and
- On February 1, 2013, Plaintiffs filed a letter with the Court seeking to now amend their Infringement and Validity Contentions. According to the letter, Plaintiffs assert that the “Second Supplemental” infringement contentions and—by extension—their current requested supplement were based on previously unknown information, namely the Indian Patent Application (D.I. 636 at 2-3), which is the same Indian Patent Application Mylan had served fifteen months earlier, on May 9, 2011, a full nine months before the Court’s deadline for amending contentions as of right. Plaintiffs also contend that their “Second Supplemental” validity contentions were based on the purported need to respond to supplemental interrogatory responses served by Mylan and Lupin (D.I. 636 at 3).

Plaintiffs’ present motion is a last-minute attempt to correct their previous failures to obtain permission to amend their contentions. [REDACTED]

REDACTED

[REDACTED] Moreover, they now cite to an Indian Patent Application, which is yet to be approved and describes a then-untested product,

² The Declaration of George J. Barry III (“Barry Decl.”), attesting to the facts in this letter, has been filed concurrently herewith.

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as factual evidence in support of this argument. Plaintiffs fail to point out that they possessed the Indian Patent Application for nearly two years before the motion presently before the Court and, in fact, nearly one year before they amended their infringement contentions as of right in accordance with the Court's previous Amended Scheduling Order.

Plaintiffs' eleventh-hour attempt also to expand their validity contentions is likewise unwarranted. They simply cannot reasonably demonstrate the diligence and good cause required by Rule 3.7. Plaintiffs fail to offer any authority permitting a party to amend its contentions in response to supplemental discovery responses, the sole basis Plaintiffs cite for amending their invalidity contentions. Moreover, they cannot reasonably explain their delay in finally seeking the Court's permission to supplement or amend contentions, which were final as of the February 29, 2012, Court-ordered deadline.

Even if Plaintiffs could meet the standard of Rule 3.7, the prejudice to Mylan at this late date would far outweigh Plaintiffs' need to amend. Therefore, Mylan respectfully submits, Plaintiffs should not be permitted to supplement their contentions. For the reasons set forth herein, the Court should deny Plaintiffs' request for leave to amend their contentions.

II. Legal Standard

Local Patent Rule 3.6 requires Plaintiffs to disclose detailed invalidity contentions early in the litigation. The purpose of this disclosure is to "require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharms., Inc. v. Sandoz Inc.*, No. 08-5974-GEB, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, No. C-95-1987-FMS, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)). To ensure that Plaintiffs' Rule 3.6 contentions serve this purpose, Plaintiffs can only amend their contentions upon "a timely application and showing of good cause." L. Pat. R. 3.7. Plaintiffs must also demonstrate *diligence* in investigating their positions and updating their contentions. *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006). The Local Patent Rules' philosophy regarding contention amendments is "*decidedly conservative*" in contrast to the more liberal standard applied to amending pleadings. *King Pharms.*, 2010 WL 2015258, at *4 (emphasis added). Plaintiffs cannot make the showings of good cause and diligence required to amend its contentions.

To amend their Local Patent Rule 3.6 contentions, Plaintiffs must satisfy the good cause requirement of Local Patent Rule 3.7. Plaintiffs cannot do so. Local Patent Rule 3.7 identifies the following four examples of circumstances that may support a finding of good cause, none of which exist in this case:

- (a) a claim construction by the Court different from that proposed by the party;
- (b) recent discovery of material prior art despite earlier diligent search;

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- (c) recent discovery of non-public information about the Accused Instrumentality which was not discovered, despite diligent efforts, before the service of the Infringement Contention; and
- (d) disclosure of an asserted claim and infringement contention by a Hatch-Waxman Act defendant under L. Pat. R. 3.6(f) that requires a response by plaintiff because it was not previously presented or reasonably anticipated.

L. Pat. R. 3.7. The facts in this case are not analogous to any of the examples of good cause provided by the Local Patent Rules.

Plaintiffs must also show that they have been diligent in seeking to amend their invalidity contentions. *O2 Micro Int'l*, 467 F.3d at 1366 (interpreting the Northern District of California's local patent rules, upon which this District's local patent rules were patterned, and holding that "'good cause' requires a showing of diligence" (emphasis added)). As the parties seeking to amend their contentions, Plaintiffs carry the burden of establishing diligence. *Id.*

Even if Plaintiffs could show good cause and diligence, which seems incomprehensible, their request should be denied due to the prejudice it would cause Mylan merely one week before the close of fact discovery.³ *See, e.g., SoftVault Sys, Inc. v. Microsoft Corp.*, No. 2:06-cv-16, 2007 WL 1342554, at *2 (E.D. Tex. May 4, 2007) (denying motion to amend contentions where the court found prejudice because the amendments would "forc[e] Microsoft to incur additional expense in reassessing its invalidity analyses"). The Local Patent Rules were designed to avoid uncertainty and the prejudice that results. *O2 Micro Int'l*, 467 F.3d at 1365-66; *see also Motorola, Inc. v. Analog Devices, Inc.*, No. 1:03-CV-131, 2004 WL 5633736, at *1 (E.D. Tex. Apr. 20, 2004) ("Allowance of continuous amendments to infringement contentions and claim constructions would encourage the vexatious shuffling of positions that the local patent rules were designed to avoid." (internal quotation marks omitted)).

III. Argument

A. Plaintiffs Failed To Diligently Identify The Facts And Cannot Show Good Cause to Amend Their Contentions.

Plaintiffs incorrectly claim to have timely sought to amend their Invalidity Contentions once they were aware of the Indian Patent Application. The record, however, reflects a clear lack of diligence. Consequently, Plaintiffs have waived their right to amend their contentions.

³ Plaintiffs' previous failures to obtain leave of Court rendered their post-February 29, 2012, amendments to their contentions completely void. There simply was no need—or opportunity—for Mylan to address or challenge the previous amendments.

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On May 9, 2011, Mylan produced the Indian Patent Application filed by Matrix to Plaintiffs. This was over nine months before Plaintiffs' February 29, 2012, filing of their Infringement Contentions and nearly two years before their new claim to amend based upon what they characterize as newly discovered facts. Plaintiffs cannot now, nearly two years after possession of this document, argue that they have been diligent in attempting to amend their contentions based on this document. It is in fact clear they have waived the right to make any such amendments. If Plaintiffs found the Indian Patent Application factually useful, Plaintiffs had the obligation to include these amendments in their February 29, 2012 Infringement Contentions. Having possessed the document for nineteen months, Plaintiffs' claims to ignorance and diligence ring hollow. *See Google, Inc. v. Netlist, Inc.*, No. C-08-4114-SBA, 2010 WL 1838693, at *2 (N.D. Cal. May 5, 2010) ("The critical issue is not *when* [the party seeking to amend its contentions] discovered this information, but rather, whether [it] *could have* discovered it earlier had it acted with the requisite diligence." (emphasis added)).

In sum, Plaintiffs' failure to assert the Indian Patent Application until now, **nineteen months** after its production and **twelve months** after Plaintiffs amended their contentions as of right and chose not to include the Indian Patent Application, shows a clear lack of diligence. In *Google*, for example, the court denied a Motion for Leave to Amend Infringement Contentions filed shortly before the close of discovery in a situation where the party seeking leave showed more diligence than the circumstances presently before the Court in this case. *Id.* at 7. Specifically, the defendant in *Google* argued that it acted diligently with respect to its proposed amendments because it only recently discovered non-public information to support such contentions through Rule 30(b)(6) depositions taken one to two months prior to the proposed amendment. *Id.* The court, however, considered the critical issue as not when the new information was discovered, but rather, whether the defendant could have discovered it earlier had it acted with the requisite diligence. *Id.* The court stated that discovery opened over a year prior to the proposed amendments and a significant portion of the documents were produced approximately **nine to eleven months** prior to the proposed amendments. *Id.* (emphasis added). The court found that more than ample opportunity existed earlier in the litigation to discover the non-public documents and ascertain whether they disclosed a basis for additional infringement contentions. *Id.* Given these facts, the court denied the Motion for Leave to Amend Infringement Contentions. *Id.* at 9.

This lack of diligence alone provides sufficient grounds for the Court to reject Plaintiffs' request for leave to amend their infringement contentions. *O2 Micro Int'l*, 467 F.3d at 1368 (finding it unnecessary to consider prejudice because defendant "did not act diligently in moving to amend its infringement contentions"). In *O2 Micro Int'l*, the court specifically rejected O2 Micro's argument that "good cause" must exist for amending its infringement contentions, without regard to its diligence in doing so, simply because new evidence was revealed during discovery. The court noted that "good cause" requires a showing of diligence. *Id.* at 1366. Specifically, in *O2 Micro Int'l*, the Federal Circuit affirmed the district court's finding of no diligence where, under O2 Micro's own facts, waited three months after discovering the

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information it sought to include in its amended contentions. In the present case, Plaintiffs have had possession of the Indian Patent Application for *nineteen months*. Plaintiffs, like the party seeking to amend in *O2 Micro Int'l*, have failed to demonstrate diligence. Rather, by failing to include this information in their previous amendment, which was still twelve months after they were provided the Indian Patent Application, Plaintiffs at the very least waived their right to amend to include reference to the same.

Moreover, with respect to their validity contentions, Plaintiffs' attempt to now, just weeks before the close of fact discovery, introduce two entirely new sections into their Validity Contentions clearly shows a lack of diligence and good faith. Plaintiffs cannot use the provisions of Local Patent Rule 3.7 to amend their contentions simply because Defendants provided arguments in their supplemental interrogatory responses, arguments that they incorrectly claim to have now only heard for the first time. However, Plaintiffs were aware of these and several other invalidity arguments early on in this case and even earlier from Lupin, who was first sued by Plaintiffs in 2009. Local Patent Rule 3.7 identifies four examples of circumstances that may support a finding of good cause and Plaintiffs have failed to identify any of these reasons that are analogous to the facts in this case.

B. Mylan Would Suffer Undue Prejudice If Plaintiffs Were Granted Leave To Belatedly Amend Their Invalidity Contentions.

Given that Plaintiffs failed to show good cause to belatedly amend their contentions, the Court need not reach the issue of prejudice. *O2 Micro Int'l*, 467 F.3d at 1368. However, Mylan's prejudice resulting from Plaintiffs' undue delay in amending their contentions is clearly another reason why Plaintiffs' request should be denied.

On February 29, 2012, Mylan received Plaintiffs' Supplemental Infringement Contentions and on March 20, 2012, nearly a month past the Court-ordered deadline and without seeking leave of Court, Plaintiffs served ineffectual "responsive" Validity Contentions purportedly responding to validity contentions Mylan had served *eighteen* months earlier in September 2010 (D.I. 379). If Plaintiffs were permitted to belatedly amend their contentions as it seeks, Mylan would be forced to expend significant resources revising its positions and litigation strategy that have been long established in this case, which weighs against Plaintiffs' motion. See *SoftVault Sys.*, 2007 WL 1342554, at *2 (finding prejudice where allowing amendment would "forc[e] Microsoft to incur additional expense in reassessing its invalidity analyses"). Furthermore, the positions set forth by Plaintiffs with respect to the Indian Patent Application impute facts to Mylan's ANDA product that are unfounded. Finally, this case has already undergone extensive extensions to the discovery schedule and Plaintiffs' amendments would only serve to unjustifiably extend discovery even further. If Plaintiffs' amendments were to be allowed Mylan should also be permitted to amend its contentions within the spirit of Rule 3.7, which would serve to prolong discovery even further.

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The Local Patent Rules were designed precisely to avoid this sort of uncertainty and prejudice that results from such dilatory conduct. *O2 Micro Int'l*, 467 F.3d at 1365-66; *see also Motorola, Inc. v. Analog Devices, Inc.*, No. 1:03-CV-131, 2004 WL 5633736, at *1 (E.D. Tex. Apr. 20, 2004) (“Allowance of continuous amendments to infringement contentions and claim constructions would encourage the vexatious shuffling of positions that the local patent rules were designed to avoid.” (internal quotation marks omitted)). Indeed, Plaintiffs have signaled their intention to change their contentions again later in the case by improperly reserving the right to do so irrespective of the Local Patent Rules or the Court’s rulings. Such attempts to “reserve” the right to continuously amend contentions inherently violate the Local Patent Rules. *See Convolv, Inc. v. Compaq Computer Corp.*, No. 00 Civ. 5141-GBD-JCF, 2006 WL 2527773, at *4--5 (S.D.N.Y. Aug. 31, 2006) (holding that reserving the right to amend violated the purpose of the Local Patent Rules as well as the scheduling order).

C. Public Policy Does Not Support Amendment.

Plaintiffs assert that as a matter of public policy, Local Patent Rule 3.7 is not a strait-jacket and they should be permitted to present all their factual evidence. The right of district courts to limit contentions via a rule such as Local Patent Rule 3.7 has been settled by the Federal Circuit, which held that local patent rules can legitimately require parties in patent cases to provide their invalidity and infringement contentions early on and proceed with diligence in amending those contentions, without running afoul of the Federal Rules of Civil Procedure:

[W]e see nothing in the Federal Rules that is inconsistent with local rules requiring the early disclosure of infringement and invalidity contentions and requiring amendments to contentions to be filed with diligence. If the parties were not required to amend their contentions promptly after discovering new information, the contentions requirement would be virtually meaningless as a mechanism for shaping the conduct of discovery.

O2 Micro Int'l, 467 F.3d at 1366 (considering the validity of the Northern District of California's local patent rules, upon which this District's local patent rules were patterned). Allowing Plaintiffs to freely amend their contentions, particularly without diligence and lack of prejudice, would be contrary to the intentions of Local Patent Rule 3.7. Plaintiffs have failed to comply with Rule 3.7 and have articulated no extraordinary circumstances that would even arguably warrant deviating from the Rules in this case.

D. Conclusion.

The Local Patent Rules, particularly as applied in Hatch-Waxman litigation, require parties to stake out their claims and defenses early in discovery and require Plaintiffs to show good cause to add previously undisclosed defenses and arguments. Plaintiffs have failed to establish good cause under the present circumstances. Moreover, the amendments Plaintiffs seek

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would unduly prejudice Mylan, which relied on Plaintiffs' existing contentions in preparing its litigation strategies. For these reasons, Mylan respectfully requests that this Court deny Plaintiffs' request for leave to amend their invalidity contentions.

Furthermore, although Mylan does not believe that Plaintiffs should be allowed to amend their contentions at this late stage, for the foregoing reasons detailed herein, Mylan respectfully requests that it be allowed to respond to any granted amendment in order to reduce any prejudice resulting therefrom.

Respectfully submitted,

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cc: All Counsel of Record (via email and ecf)